



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,360	09/15/2003	Jian-yun Dong	22488-756	1654

7590
Dr. Benjamin Adler
Adler & Associates
8011 Candle Lane
Houston, TX 77071

11/28/2007

EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

ART UNIT	PAPER NUMBER
----------	--------------

1648

MAIL DATE	DELIVERY MODE
-----------	---------------

11/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/663,360

Applicant(s)

DONG, JIAN-YUN

Examiner

Louise.Humphrey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-41, 43-54 and 56-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 24, 33, 34, 37 and 39 is/are rejected.
- 7) ☒ Claim(s) 19-23, 25-32, 35, 36, 38, 40, 41, 43-54 and 56-61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the amendment filed 26 September 2007. Claims 5, 42 and 55 have been cancelled. Claims 1-4, 6-41, 43-54 and 56-61 are pending and currently examined.

Claim Objections

The objection to claim 38 is withdrawn in response to Applicant's amendment.

The objection to claim 40 is maintained because the word "titer" is in noun form only and the "titering" is not an appropriate word to recite the claimed active method step. Applicant is advised to replace the phrase "titering for" with a word such as "counting," "measuring," or "determining."

Claims 19-23, 25-32, 35, 36, 38, 40, 41, 43-54, 56-61 are objected to for depending from rejected claims.

Double Patenting

The nonstatutory double patenting rejection of claims 1, 2, 8-12, 15, 18, 33 and 34 as being unpatentable over claims 61-66 of U.S. Patent No. 6,900,010 B2 is **maintained** in view of Japour *et al.* (1993).

The nonstatutory double patenting rejection of claims 1-18, 24, 33, 34, 37 and 39 as being unpatentable over claims 1, 4, 5, 9-24, and 26-28 of U.S. Patent No. 6,884,576 B2 is **maintained** in view of Japour *et al.* (1993).

Applicant argues that the instant claims recite the extra step of comparing the expression level of the reporter gene in an HIV sample with that in a reference HIV sample. However, the reference HIV testing step is an alternative method step according to the instant claim language. Therefore, this limitation is optional and therefore is not required to be explicitly claimed in the conflicting patents. Secondly, even though the patent claims do not explicitly recite comparing the expression level of the reporter in an HIV sample with that in a reference HIV sample, it is routinely used in the art. Japour *et al.* (1993) describe a cell culture assay for determination of drug resistance of clinical HIV isolates in parallel with an assay for a panel of well-characterized reference HIV-1 isolates that are both drug-susceptible and drug-resistant. See page 1096, 2nd column.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the method in the claims of U.S. Patent No. 6,900,010 B2 and 6,884,576 B2 such that no change or an increase in the reporter gene expression in the HIV sample when compared with a wild-type or non-drug-resistant strain of HIV indicates drug resistant of the HIV in the sample. One having ordinary skill in the art would have been motivated to make such a modification to increase the validity of the drug resistance assay method, as per the teachings of Japour *et al.* Therefore, the patented claims render obvious the instant claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. §112:

Art Unit: 1648

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-61 under 35 U.S.C. §112, second paragraph, as being indefinite is **maintained** in response to the Applicants' amendment.

Claim 1 recites contacting the cell culture with a first sample containing HIV "or with a second sample containing reference HIV strain." The word "or" renders the claim indefinite because it is unclear whether the limitations following the word are part of the claimed invention. See MPEP § 2173.05(d). Furthermore, the phrase "reference HIV strain" is indefinite. A reference strain can be laboratory-adapted or clinically isolated, wild type or mutant, drug-susceptible or drug-resistant. It is unclear which HIV strain qualifies as the reference for the instantly claimed method. Applicant is advised to insert the strain name, HLTV-IIIB, as disclosed in the specification on page 16 and 55.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1648


the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.
Primary Examiner
21 November 2007



Louise Humphrey, Ph.D.
Assistant Examiner